REMARKS

Applicants respectfully request consideration of this application.

Drawings

The drawings are objected to as failing to comply with 37 C.F.R. 1.84(p)(5) because the reference number (10) for the guidewire is not shown in the drawings. Figure 1 has been objected to because the reference number (11) twice marks two different components of the device. Appropriate corrections have been made to the drawings and are attached to this response.

Specification

The specification has been objected to as failing to provide antecedent basis for the claimed subject matter. In particular, the Office Action states that the specification fails to provide proper antecedent basis for an optical fiber "marker with a radiopaque substance" as recited in claim 18. Applicants respectfully submit that proper antecedent basis for an optical fiber marker with a radiopaque substance may be found on paragraph **[0037]** of the filed application, which states in part, "The most distal section 21 of the flexible coil 15 may be made of radiopaque material, such as platinum or platinum-nickel alloys, to facilitate the fluoroscopic observation therof while it is disposed within a patient's body."

Office Action Rejections Summary

Claims 1, 2, and 5 have been rejected to under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,951,482 to Winston et al. (hereinafter "Winston"). Claims 1 – 7, 10, and 18 have been rejected to under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,941,473 to Tenerz et al. (hereinafter "Tenerz"). Claims 8, 9, and 22 – 25 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Tenerz. Claims 11 – 17,

and 19 – 21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Tenerz in view of U.S. Patent 5,980,471 to Jafari (hereinafter "Jafari").

Status of Claims

Claims 1 – 28 remain pending in the application. Claims 1, 6, 11, 21, 22, and 24 have been amended to define the invention more properly. The amended claims are supported by the specification. Claims 26 – 28 have been added. The new claims are supported by the specification. No new matter has been added. No claims have been canceled.

35 U.S.C. § 102 Rejections

Amended claim 1 provides:

> An apparatus comprising:
>
> ***a therapeutic guidewire having a high strength proximal core section and flexible distal core section***; and
>
> at least one optical fiber disposed through the therapeutic guidewire, the optical fiber configured to provide diagnostic information before, during, and after a therapeutic treatment. (emphasis added)

Amended claim 6 provides:

> An apparatus comprising:
>
> a therapeutic guidewire ***having a high strength proximal core section and flexible distal core section, the therapeutic guidewire*** configured to operatively receive a treatment device;
>
> a polymeric jacket disposed about the distal core section; and
>
> at least one optical fiber disposed within the therapeutic guidewire to sense vessel and blood characteristics. (emphasis added)

Winston discloses a guide wire assembly 20 that includes a control element 26 and a guide wire 28. Guide wire 28 has a first end 30 and a head 32, and includes a bore 34

extending between first end 30 and head 32. Guide wire first end 30 is coupled to control element 26 and guide wire second end 32 is positioned within an interior 36 of blood vessel 24 adjacent tissue through which guide wire 28 is to be advanced. Nothing in Winston teaches a therapeutic guidewire having a high strength proximal core section and flexible distal core section. (Winston, col. 4, lines 23 – 30, and FIG. 1).

In contrast, claim 1 recites in part, "a therapeutic guidewire having a high strength proximal core section and flexible distal core section." Therefore, Applicants respectfully submit that claim 1 is not anticipated by Winston under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claim. Claims 2 and 5 depend either directly or indirectly from independent claim 1, and thus include the limitation of "a therapeutic guidewire having a high strength proximal core section and flexible distal core section." As such, Applicants respectfully submit that claims 2 and 5 are also not anticipated Winston under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claims.

Tenerz discloses a welded joint for connecting a pressure sensor to an optical fiber within a guide wire. In this region the guide wire is easily flexible and resilient. The easily flexible part is usually 5 – 20 cm long and merges into a stiffer part towards its proximal end. The stiffer part may comprise a more tightly wound wire, or one that is thicker and thereby stiffer, or a thin-walled metal tube. (Tenerz, col. 2, lines 25 – 33, and FIG. 1). Nothing in Tenerz teaches a therapeutic guidewire having a high strength proximal core section and flexible distal core section. (Winston, col. 4, lines 23 – 30, and FIG. 1).

In contrast, claims 1 and 6 recite in part, "a therapeutic guidewire having a high strength proximal core section and flexible distal core section." Therefore, Applicants respectfully submit that claims 1 and 6 are not anticipated by Tenerz under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claim. Claims 2 – 5

and 18 depend either directly or indirectly from independent claim 1, and claims 7 and 10 depend from independent claim 6, and thus include the limitation of "a therapeutic guidewire having a high strength proximal core section and flexible distal core section." As such, Applicants respectfully submits that claims 2 – 5, 7, 10, and 18 are also not anticipated Tenerz under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claims.

35 U.S.C. § 103 Rejections

Claims 11 – 17, and 19 – 21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Tenerz in view of Jafari. Claims 11 – 17 and 19 – 21 depend either directly or indirectly from independent claim 6, and thus includes all the limitations of the base claim. Amended independent claim 6 provides:

> An apparatus comprising:
>
> a therapeutic guidewire having a high strength proximal core section and flexible distal core section, the therapeutic guidewire configured to operatively receive a treatment device;
>
> ***a polymeric jacket disposed about the distal core section***; and
>
> at least one optical fiber disposed within the therapeutic guidewire to sense vessel and blood characteristics. (emphasis added)

Nothing in Tenerz teaches or suggests a polymeric jacket disposed about a distal core section. Jafari discloses a guidewire 10 having conventional features. The distal core portion 12 has at least one tapered section 21 which becomes smaller in the distal direction. A helical coil 22 is disposed about the distal core section 12 and is secured by its distal end to the distal end of shaping ribbon 23 by a mass of solder which forms rounded plug 24 when it solidifies. The proximal end of the helical coil 22 is secured to the distal core section 12 at a proximal location 25 and at intermediate location 26 by a suitable solder. The proximal end of the shaping ribbon 23 is secured to the distal core portion 12 at the same

intermediate location 26 by the solder. Nothing in Jafari teaches or suggests a polymeric jacket disposed about a distal core section. As such, Jafari fails to cure the deficiency of Tenerz.

It is respectfully submitted that Tenerz and Jafari do not teach or suggest a combination with each other. It would be impermissible hindsight, based on Applicant's own disclosure, to combine Tenerz and Jafari.

Applicants respectfully submit that there is no motivation to combine Tenerz and Jafari. The Office Action states that it would have been obvious to a person of ordinary skill in the art "to incorporate the guidewire structure limitation of Jafari into the system of Tenerz because the structure of Jafari improves on the movement of a guidewire within the vascular body" (Office Action dated 12/23/03, page 7). Here, the Office Action merely states an advantage of substituting the guidewire from Jafari, with the catheter by Tenerz, without explaining what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination.

Even if Tenerz and Jafari were combined, it would still not result in the limitations of claim 6. As stated above, claim 6 includes the limitation of "a polymeric jacket disposed about the distal core section." The combination of Tenerz and Jafari does not teach this limitation. As such, the combination cannot be interpreted to disclose the limitations of claims 6. Therefore, Applicants respectfully request the withdrawal of the rejection of the claims 11 – 17 and 19 – 21 under 35 U.S.C. § 103(a) over the combination.

Claims 8, 9, and 22 – 25 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Tenerz. Claims 8 and 9 depend from independent claim 6 and thus include the limitation of "an elongated guidewire body having a flexible distal core section axially coupled to a high strength proximal core section." As discussed above, nothing in

Tenerz teaches or suggests this limitation. As such, Applicants respectfully submit claims 8 and 9 are not unpatentable under 35 U.S.C. §103(a) over Tenerz.

Amended independent claim 22 provides:

> A system for sensing vessel and blood characteristics, the system comprising:
>
> a data processing system; and
>
> an apparatus coupled to the data processing system, the apparatus comprising ***a therapeutic guidewire having a high strength proximal core section and flexible distal core section*** and at least one optical fiber disposed therein, the optical fiber capable to sense vessel and blood characteristics.
>
> (emphasis added)

Amended independent claim 24 provides:

> A method of sensing vessel and blood characteristics, the method comprising:
>
> inserting an apparatus into a vasculature of a patient, the apparatus comprising ***a therapeutic guidewire having a high strength proximal core section and flexible distal core section*** and at least one optical fiber disposed therein, the optical fiber configured to provide diagnostic information before, during, and after the therapeutic treatment;
>
> advancing the apparatus to a desired location in the vasculature;
>
> operating a data processing system coupled to the apparatus such that light signals are transmitted to the desired location in the vasculature and reflected light signals are collected by the data processing system; and
>
> processing the reflected light signals to provide vessel and blood characteristics. (emphasis added)

As discussed above, nothing in Tenerz teaches or suggests the emphasized limitation of "a therapeutic guidewire having a high strength proximal core section and flexible distal core section."

The Office Action states, "It would have been inherently obvious to a person of ordinary skill in the art to provide said system and method steps of data processing because such is essential to able to read/interpret the diagnostic data received" (Office Action dated 12/23/03, page 5). Here, the Office Action merely states an advantage of Tenerz without explaining what specific understanding or technological principle within the knowledge of one of ordinary skill in the art.

In conclusion, Applicants respectfully submit that in view of the amendments and arguments set forth herein, the applicable rejections have been overcome. If the allowance of these claims could be facilitated by a telephone conference, the Examiner is invited to contact Suk Lee at (408) 720-8300. If there are any additional charges, please charge our Deposit Account No. 02–2666.

Respectfully submitted,
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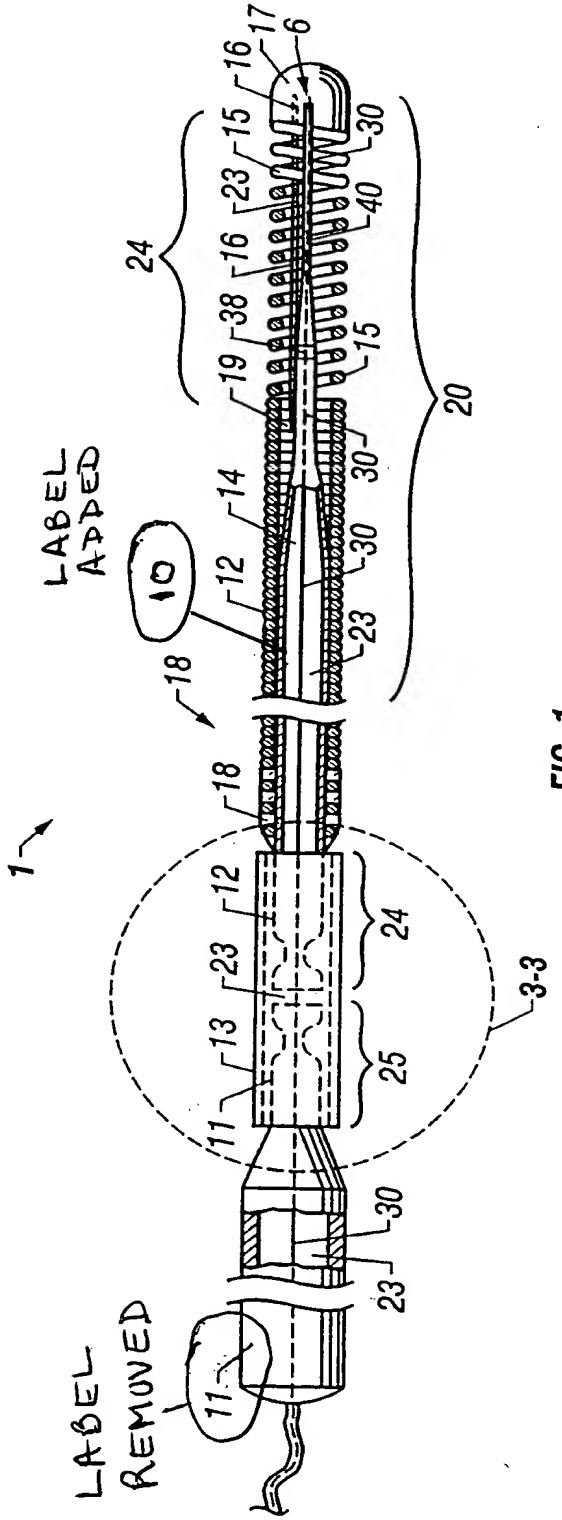

FIG. 1

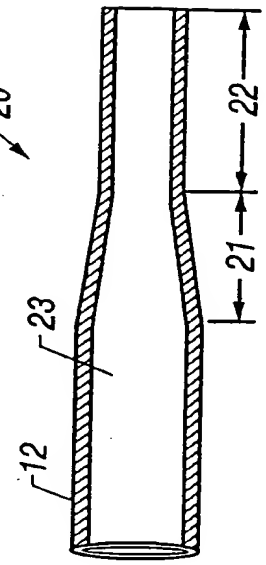

FIG. 2

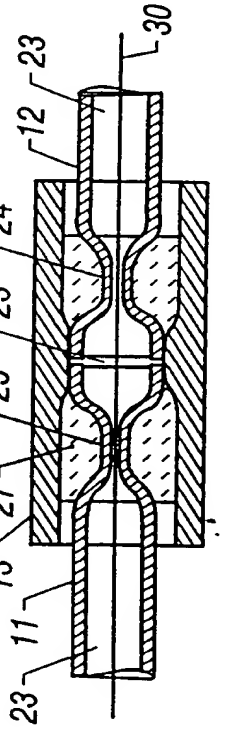

FIG. 3